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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/698,289

10/31/2003

David E. Wolf

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1624

27791 7590 10/18/2007

ALLISON JOHNSON, P.A.  
LAKE CALHOUN EXECUTIVE CENTER  
3033 EXCELSIOR BLVD., SUITE 467  
MINNEAPOLIS, MN 55416

EXAMINER

YANG, NELSON C

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

10/18/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/698,289

Applicant(s)

WOLF, DAVID E.

Examiner

Nelson Yang

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1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-90 is/are pending in the application.
- 4a) Of the above claim(s) 1, 43, 48-55, 66-83, 87 and 88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-42, 44-47, 56-65 and 84-92 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892).
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Response to Amendment*

1. Applicant's amendment of claim 30 is acknowledged and has been entered.
2. Applicant's addition of claims 91 and 92 is acknowledged and has been entered.
3. Claims 2-47, 56-65, 84-86, 88-92 are currently under examination.
4. Claims 1, 48-55, 79-83, 87 have been withdrawn.

### *Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 30, 2, 3, 5-11, 13-19, 22, 25, 26, 31-42, 44-47, 56-65, 84-86, 89-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz [US 6,256,522] in view of Empedocles et al. [US 2002/0031783].

With respect to claims 30, 56, 91, and 92, Schultz teaches a sensor comprising a gel comprising molecules of receptor material covalently bonded to strands of polymers (column 6, lines 1-11), encapsulated in a semi-permeable membrane (column 5, lines 45-65). Schultz also teaches a light source for shining excitation light (column 7, lines 10-15) and detection means for measuring fluorescence (column 8, lines 28-38). Schultz further teaches that more than two different receptor materials and associated dyes can be used to detect more than two analytes

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(column 13, lines 10-21). Schultz fails to teach a chip comprising a first, second and third detector to detect the additional dyes.

Empedocles et al. teach a sensor comprising a polymeric matrix (para. 0081), multiple fluorophores (para. 0107), a membrane comprising a 7 micron layer of parylene (para. 0151), excitation sources (para. 0019), and multiple detectors, one for each separate fluorophore (para. 0107, 0145, fig. 2A-2E), and a processor coupled to the detectors (para. 0065) for determining the results of the assay (para. 0040) and further discloses that the invention allows for simultaneously imaging of identifiable spectra throughout the detection regions.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the detectors of Empedocles et al. in the sensor of Schultz, in order to the simultaneously image identifiable spectra throughout the detection regions, which would be allow for detection of more analytes in a faster and more efficient manner.

7. With respect to claims 2, 3, 31, 32, 41, 58, 59, Schultz discloses that the sensor is capable of excitation and detecting ultraviolet light (column 8, lines 28-37), capable of exciting and detecting light transcutaneously such as from under the skin (column 7, lines 10-20).

8. With respect to claims 33, 57, Empedocles et al. teach that the sensor has a networking connection (para. 0100), and therefore would be capable of transmitting signals to a remote location.

9. With respect to claims 5-6, 34, Empedocles et al. teach that the sensor comprises 10 filters (para. 0116).

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10. With respect to claims 7-8, 35-37, Empedocles et al. teach that the sensor may comprise a system of dichroic mirrors (about 10) (para. 0116) for selectively transmitting signals (para. 0116, 0137).
11. With respect to claims 9-11, 38-40, Schultz discloses optical fibers connected to a light source and detection means (column 4, lines 40-45).
12. With respect to claim 13, Schultz discloses that the dye labeled substance is mobile within the sensor (fig. 1, column 9, lines 33-42).
13. With respect to claims 14, 15, Empedocles et al. teach that the sensor comprises a processor (para. 0040) and has a networking connection (para. 0100), and therefore would be capable of transmitting signals to a remote location.
14. With respect to claims 16-17, 44-47, Empedocles et al. teach that the sensor calculates an intensity and ratio among the various wavelengths to determine spectral characteristics (property of analyte) (para. 0089), such as by different concentrations (para. 0078). Therefore, the sensor would be capable of receiving data from the first, second and third wavelengths and correcting the intensity at the second wavelength based on the intensity at the third wavelengths.
15. With respect to claims 18, 19, Empedocles et al. teach that the sensor comprises machine-readable code of program instructions (para. 0101).
16. With respect to claim 22, Schultz discloses that the system detects glucose (claim 2).
17. With respect to claim 25, Empedocles et al. teach that the sensor is capable of simultaneously imaging of identifiable spectra through a detection region (para. 0018).
18. With respect to claim 26, Empedocles et al. teach that the sensor is capable of pulsing light with pulsed lasers (para. 0098).

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19. With respect to claim 60, Empedocles et al. teach that the sensor comprises a processor for determining the results of the assay (para. 0040).

20. With respect to claim 61, Empedocles et al. teach that the sensor is capable of detecting spatially resolved labels (para. 0067).

21. With respect to claims 62-63, Empedocles et al. teach that the sensor comprises a processor coupled to the detector (para. 0065), which one of ordinary skill in the art would know would comprise a clock and which would require an A/D converter to change the analog signal to a digital signal the processor would be capable of analyzing.

22. With respect to claim 64, Empedocles et al. teach that the sensor has a networking connection (para. 0100), and therefore would be capable of transmitting signals to a remote location.

23. With respect to claim 65, Empedocles et al. teach that the sensor calculates an intensity and ratio among the various wavelengths to determine spectral characteristics (property of analyte) (para. 0089), such as by different concentrations (para. 0078).

24. With respect to claim 84, Empedocles et al. teach that the sensor may comprise light emitting diodes (para. 0098).

25. With respect to claims 85-86, Empedocles et al. teach that the sensor comprises liquid crystal filters for scanning a surface (para. 0109).

26. With respect to claim 88, Empedocles et al. disclose dichroic mirrors (para. 0116).

27. With respect to claims 89, 90, Empedocles et al. teach that the sensor may comprise a diode array or CCD (para. 0099).

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28. Claims 12, 20, 21, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Empedocles et al. [US 2002/0031783] in view of Martin et al. [US 2002/0016535].

With respect to claims 12, 20, 23, Schultz et al. disclose the invention as discussed above, but fail to teach that the instructions to administer insulin, glucose, or a combination thereof, but fail to teach that the sensor detects glucose, provides an alarm, or administers insulin.

Martin et al., however, teach a glucose sensor incorporated with an insulin pump (para. 0061) in order to provide a glucose measuring and insulin delivery system that allow the return of near normal functioning of the body (para. 0061).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the device of Schultz et al. to measure glucose as suggested by Martin et al., in order to allow the return of normal function to the bodies of patients with diabetes.

29. With respect to claim 21, Martin further teach an alarm when a glucose levels are becoming to high or low or when there is no response (para. 0058), which ensures that the sensor is working properly (para. 0053).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated an alarm in the device of Empedocles et al., as suggested by Martin et al., in order ensure that the sensor is working properly.

30. Claims 30, 2-4, 9-11, 13-19, 22, 24, 28, 29, 31, 32, 38-41, 45, 46, 56-65, 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz [US 6,256,522] in view of Zenhausern [US 2002/0094531].

With respect to claims 30, 56, 91, 92, Schultz teaches a sensor comprising a gel comprising molecules of receptor material covalently bonded to strands of polymers (column 6, lines 1-11), encapsulated in a semi-permeable membrane (column 5, lines 45-65). Schultz also teaches a light source for shining excitation light (column 7, lines 10-15) and detection means for measuring fluorescence (column 8, lines 28-38). Schultz further teaches that more than two different receptor materials and associated dyes can be used to detect more than two analytes (column 13, lines 10-21). Schultz fails to teach a chip comprising a first, second and third detector to detect the additional dyes.

Zenhausern, however, teaches a sensor comprising a polymeric matrix (para. 0077), multiple fluorophore markers (para. 0021) comprising four spectrally resolvable dyes (para. 0073), a membrane comprising (para. 0077), a laser (excitation source) (para. 0077), and a multiple sensor array as the detector (para. 0025), and an electronic processing means (para. 0077) and database software for archiving and graphical display (para. 0077). Zenhausern also teaches a multivariate detector comprising an array of sensing devices (para. 0029), wherein each sensor has its own signal connection and its own sensitivity (para. 0058). Zenhausern further teaches that multivariate analysis allows for useful information to be extracted from the detector (para. 0025).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the multivariate detector of Zenhausern in the invention of Schultz, in order to extract useful information, while also providing a greater versatility and flexibility in performing different types of detection using the different sensors.



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31. With respect to claims 2, 3, 31, 32, 41, 58, 59, Schultz discloses that the sensor is capable of excitation and detecting ultraviolet light (column 8, lines 28-37), capable of exciting and detecting light transcutaneously such as from under the skin (column 7, lines 10-20).

32. With respect to claims 4, 33, 57, Zenhausern teaches a transmission means capable of transmitting a signal between the multivariate detector and a data acquisition system (para. 0051), wherein the communications method may be wireless (para. 0059).

33. With respect to claims 9-11, 38-40, Schultz discloses optical fibers connected to a light source and detection means (column 4, lines 40-45).

34. With respect to claim 13, Schultz discloses that the dye labeled substance is mobile within the sensor (fig. 1, column 9, lines 33-42).

35. With respect to claim 14, Zenhausern teaches database software for archiving and graphical display (para. 0077).

36. With respect to claim 15, Zenhausern teaches a transmission means capable of transmitting a signal between the multivariate detector and a data acquisition system (para. 0051).

37. With respect to claims 16-19, Zenhausern teaches comparing the analysis of the signals at several wavelengths with the properties of the analyte as a result of surface interactions (para. 0034), such as changes in concentration (claim 13).

38. With respect to claim 22, Zenhausern teaches that the sensor can detect proteins (para. 0026).

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39. With respect to claim 24, Zenhusern teaches that the sensor is semiconductor based (para. 0040) and located on a substrate (para. 0077), which would make the substrate a semiconductor wafer upon which the detectors would be located.

40. With respect to claims 25, 27, Zenhusern teaches a multiplexer for simultaneous analysis of the data (para. 0090), and which would be capable of phase locking the counting of signals at the detectors.

41. With respect to claims 28, 29, Zenhusern teaches a pump (para. 0080), which would be capable of drawing interstitial fluid or blood.

42. With respect to claims 45, 46, Zenhusern teaches comparing the analysis of the signals at several wavelengths with the properties of the analyte as a result of surface interactions (para. 0034), such as changes in concentration (claim 13).

43. With respect to claims 60, 61, Zenhusern teaches an electronic processing means (para. 0077) and database software for archiving and graphical display (para. 0077).

44. With respect to claim 62, Zenhusern teaches a multiplexer which would convert the signal from analog to digital before outputting the data to the computer (para. 0090).

45. With respect to claim 63, the computer taught by Zenhusern would comprise a clock (para. 0090).

46. With respect to claim 64, Zenhusern teaches a transmission means capable of transmitting a signal between the multivariate detector and a data acquisition system (para. 0051), wherein the communications method may be wireless (para. 0059).

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47. With respect to claim 65, Zenhusern teaches comparing the analysis of the signals at several wavelengths with the properties of the analyte as a result of surface interactions (para. 0034), such as changes in concentration (claim 13).

48. With respect to claim 89, Zenhusern teaches a multiple sensor array as the detector (para. 0025).

### *Response to Arguments*

49. Applicant's arguments with respect to claims 2-47, 56-65, 84-86, 88-92 have been considered but are moot in view of the new ground(s) of rejection.

### *Conclusion*

50. No claims are allowed.

51. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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52. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

53. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nelson Yang  
Patent Examiner  
Art Unit 1641

  
LONG V. LE 10/12/07  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600